**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

| IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | |
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| THIS DOCUMENT RELATES TO:<br>*The City of New York v. Abbott Laboratories, Inc., et al.* (S.D.N.Y. No. 04-CV-06054)<br>*County of Albany v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00425)<br>*County of Allegany v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06231)<br>*County of Broome v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00456)<br>*County of Cattaraugus v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06242)<br>*County of Cayuga v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00423)<br>*County of Chautauqua v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06204)<br>*County of Chemung v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06744)<br>*County of Chenango v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00354)<br>*County of Columbia v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00867)<br>*County of Cortland v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00881)<br>*County of Dutchess v. Abbott Laboratories, Inc., et al.* (S.D.N.Y. No. 05-CV-06458)<br>*County of Essex County v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00878)<br>*County of Fulton v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00519) | MDL NO. 1456<br>Civil Action No. 01-12257-PBS<br>Subcategory Case No. 03-10643-PBS<br>Judge Patti B. Saris<br>Oral Argument Requested<br>**DEFENDANT SMITHKLINE BEECHAM CORPORATION, D/B/A GLAXOSMITHKLINE'S ("GSK'S") SUPPLEMENTAL BRIEF, CONCERNING REBATE ISSUES, IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT IN THE NEW YORK COUNTY CASES** |

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| *County of Genesee v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06206)<br><br>*County of Greene v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00474)<br><br>*County of Herkimer v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00415)<br><br>*County of Jefferson v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00715)<br><br>*County of Lewis v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00839)<br><br>*County of Madison v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00714)<br><br>*County of Monroe v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06148)<br><br>*County of Nassau v. Abbott Laboratories, Inc., et al.* (E.D.N.Y. No. 04-CV-5126)<br><br>*County of Niagara v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06296)<br><br>*County of Oneida v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00489)<br><br>*County of Onondaga v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00088)<br><br>*County of Ontario v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06373)<br><br>*County of Orange v. Abbott Laboratories, Inc., et al.* (S.D.N.Y. No. 07-CV-2777)<br><br>*County of Orleans v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06371)<br><br>*County of Putnam v. Abbott Laboratories, Inc., et al.* (S.D.N.Y. No. 05-CV-04740)<br><br>*County of Rensselaer v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00422)<br><br>*County of Rockland v. Abbott Laboratories, Inc., et al.* (S.D.N.Y. No. 03-CV-7055) | |

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| *County of Saratoga v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00478)<br><br>*County of Schuyler v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06387)<br><br>*County of Seneca v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06370)<br><br>*County of St. Lawrence v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00479)<br><br>*County of Steuben v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06223)<br><br>*County of Suffolk v. Abbott Laboratories, Inc., et al.* (E.D.N.Y. No. CV-03-229)<br><br>*County of Tompkins v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00397)<br><br>*County of Ulster v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 06-CV-0123)<br><br>*County of Warren v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00468)<br><br>*County of Washington v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00408)<br><br>*County of Wayne v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06138)<br><br>*County of Westchester v. Abbott Laboratories, Inc., et al.* (S.D.N.Y. No. 03-CV-6178)<br><br>*County of Wyoming v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 03-CV-6379)<br><br>*County of Yates v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06172) | |

## Introduction and Summary of Argument

The New York County Plaintiffs continue to misinterpret and misapply this Court's WAC List Price Test in their effort to keep hundreds of GSK brand-name drugs in this case. These drugs do not belong in this case because they were sold to drug purchasers within 5% of published WACs well over 50% of the time.

GSK and the Plaintiffs agree that "purchase-based rebates," namely rebates paid to wholesalers and providers that purchase drugs, should be included in determining the net purchase price under the WAC List Price Test. Plaintiffs are now claiming, however, that an entirely different kind of rebate -- namely rebates paid to *payors* like TPPs and PBMs[1] that reimburse for drugs -- should be treated in exactly the same way under the test. Rebates to payors, however, are entirely different, because they have no effect on the net price paid by any drug *purchaser* -- which is the net price that matters under the WAC List Price Test. It therefore makes no sense to include these rebates in the net purchase price calculations under the test. Yet Plaintiffs ignore this critical distinction between rebates to purchasers and rebates to payors, and want to treat them as if they are the same.

Plaintiffs' extreme position on rebates to payors is inconsistent with the purpose of the WAC List Price Test and with the position on payor rebates previously taken here by Plaintiffs' own expert. In fact, it is so extreme that no less an authority on pharmaceutical pricing issues than M.I.T. Professor Ernst Berndt, Ph.D, has submitted an Affidavit in support of GSK's position. Dr. Berndt concludes that including rebates to

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[1] "TPPs" are third-party payors like insurance companies and employee benefit plans. "PBMs" are pharmacy benefit managers that are hired by TPPs to handle, among other things, the payment of reimbursements to pharmacies on behalf of the TPP. Rebates paid to TPPs and PBMs are generally paid by brand-name manufacturers under contracts that provide for formulary placement for their drugs.

payors in determining net price under the WAC List Price Test is inconsistent with the purpose of the test, whereas excluding them (as GSK has done) is consistent with the test and with the goal of reducing health care costs.[2] Therefore, Dr. Berndt concludes, these payor rebates should be *encouraged*, not used as a basis to cause GSK to incur greater liability and damages under the WAC List Price Test, as the New York County Plaintiffs now seek to do. Berndt Aff. (Ex. A hereto) at 29-30.[3]

There is a simple reason why rebates paid to payors should not be included in the test. The Court established the WAC List Price Test to determine whether WACs have a reasonable relationship to actual net transaction prices paid by drug *purchasers*. Thus, the proper comparison is between the published WAC and the net price the wholesaler or provider (*i.e.*, the drug purchaser) pays. Rebates paid to payors that merely reimburse providers for drugs, however, are not shared with drug purchasers and therefore have *absolutely no effect on the net purchase price* paid by any drug purchaser. The purpose of the WAC List Price Test is to compare WACs to drug purchasers' net prices -- not to an artificial net price derived by pretending that drug purchasers get payor rebates that they do not get.

In addition to fundamentally distorting the WAC list price test by seeking to include rebates that benefit payors, not purchasers, Plaintiffs now also attempt to distract

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[2] Affidavit of Ernst R. Berndt, Ph.D., dated June 29, 2009 (Berndt Aff.) (attached hereto as Exhibit A) at ¶¶ 24; 29-30. Dr. Eric Gaier, GSK's expert, has also submitted an Affidavit in which he makes the same point, among others. Second Supplemental Affidavit of Eric M. Gaier, Ph.D ("Second Suppl. Gaier Aff.") (attached hereto as Exhibit B).

[3] As discussed in Section IV below, the Plaintiffs' further compound the error of including payor rebates in their net purchase price calculations by "misallocating" those rebates in a way that artificially causes millions of purchases by retail pharmacies that did not get the rebates to "flunk" the WAC List Price Test. Ironically, this flawed attribution of rebates to purchasers who did not get them is similar to the flaws in Plaintiffs' original position on the allocation of chargebacks to all wholesaler sales -- even though Plaintiffs' expert has now (following the extensive oral argument on this issue in April 16, 2009) abandoned his original position on wholesaler chargeback allocation.

the Court with three "red herring" arguments. All of them are not only side shows, but, when properly analyzed, the facts actually support GSK's position, as follows:

1. Plaintiffs now argue that GSK's payment of utilization rebates to TPPs and PBMs -- which were made in connection with the placement of GSK drugs on a formulary and utilization of those drugs by the TPP's insureds -- was like giving discounts to physicians for physician-administered drugs and then improperly marketing the "spread" between their acquisition cost and the published AWP. This argument is baseless. In fact, as Professor Berndt points out in his Affidavit, paying rebates to PBMs and other payors (unlike providing discounts and marketing increased spreads to providers) actually *narrows* the difference between what providers pay and the net cost to payors of reimbursing for drugs. Payor rebates are economically beneficial to payors and ultimately to consumers, and paying them should not be condemned. Berndt Aff. (Ex. A hereto) at ¶¶ 23-30.

2. Second, Plaintiffs imply that there are still disputes that preclude summary judgment. In fact, the fundamental analysis of each side's expert has converged to the point where the only remaining issue that materially affects the outcome is whether and how to include non-mail order rebates to PBMs and TPPs in the calculation of the relevant net prices under the WAC List Price Test. Once the payor rebates are excluded and the remaining rebates are properly allocated to the purchasers who got them, all but two or three of the original 208 GSK NDCs at issue pass the test whether Dr. Gaier's most conservative approach is taken or Mr. Devor's method of applying the test is used. Second Suppl. Gaier Aff. (Ex. B hereto) at ¶¶ 14-15.

3. Finally, Plaintiffs' expert once again seeks to create the misimpression that many of the GSK drugs at issue "flunk" the "AWP Spread Test," even though GSK

has not moved on the basis of that test and need not satisfy it in order to prevail here. However, as discussed further below, once Mr. Devor's latest version of that test -- which for the first time now includes rebates to PBMs and some TPPs -- is corrected to exclude them (for all of the reasons discussed herein), the result is that all but a handful of the GSK NDCs at issue pass the AWP Spread Test as well. Second Suppl. Gaier Aff. (Ex. B hereto) at ¶¶ 19-22.

Plaintiffs have had every opportunity to mount a meritorious argument against GSK's November 2008 Motion for Partial Summary Judgment and have failed to come up with a single one. There is simply no reason for the Court to wait any longer to grant GSK's Motion.[4]

## Argument

### I. The WAC List Price Test Is Intended To Compare The Net Price Paid by Drug Purchasers (Wholesalers and Providers) with Published WACs.

This Court fashioned the WAC List Price Test (and the AWP Spread Test) for the fundamental purpose of determining whether published WACs (and formulaically-related AWPs) were reasonably tethered to, or constituted a reasonably reliable signal for, the net prices being paid by drug purchasers such as wholesalers and providers seeking reimbursement. *See generally In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d 20 (D. Mass. 2007); Berndt Aff. (Ex. A hereto) at ¶ 20. GSK understands the Court's view to be that if published WACs (or AWPs) satisfy these criteria, then payors that reimburse for brand-name drugs on the basis of WAC or AWP

[4] We note that Plaintiffs' latest brief repeatedly cites the MDL "tutorial" submission of Dr. Meredith Rosenthal, who served as the MDL plaintiffs' expert. But what the New York County Plaintiffs do not cite from Dr. Rosenthal's submission -- and what they are desperately trying to ignore -- is her statement that it is a "fact" that "for 99% of prescription drugs, AWP works." Written Tutorial of Dr. Meredith Rosenthal, dated December 3, 2004, at 3 note 2. It is time for the New York County Plaintiffs to stop trying to manipulate the application of the Court's previously-articulated tests and to face the "fact" that the GSK brand-name drugs now at issue are among the 99% of drugs for which the published pricing system has worked.

can use those published prices to make reasoned decisions about what reimbursement rates to set -- and the system will work as intended.

There has never been any dispute that, for brand name drugs, WAC relates (in some way) to the price of drugs paid by drug *purchasers*. However, Plaintiffs are saying for the first time, in effect, that WACs should reflect something very different -- namely the "net revenue received" for a drug by the drug manufacturer. Plaintiffs purport to arrive at this figure by deducting from GSK's revenues for the relevant drugs all discounts, chargebacks, credits, returns and several different kinds of rebates. They include in these deductions the sometimes substantial rebates paid to PBMs and third-party payors which (as discussed further below) have absolutely no impact on the drug purchaser's net price. Such an interpretation, if adopted, would require WACs to be pre-set at levels that would be far below what any wholesaler or retail pharmacy pays for a drug. Such a WAC, of course, would not accomplish the Court's purpose of providing a reasonably reliable signal for either a wholesaler's or a provider's purchase price, and would be useless to payors trying to use WACs (or formulaically related AWPs) as such a signal for reimbursement purposes.

In addition to being entirely inconsistent with any reasonable interpretation of WAC or the purpose of the Court's WAC List Price Test, Plaintiff's "net revenue" approach is so bizarre that (a) it is not fully adopted even by Plaintiffs expert here,[5] and

[5] "Net revenue" or "net turnover," as demonstrated by the GSK Form 20-F attached to Ms. Cicala's latest affidavit, is an accounting term used to describe the net amount realized by a manufacturer after deduction from gross sales of all chargebacks, rebates and discounts to government and state programs and other payors, cash discounts, customer returns, prior year adjustments and other items. *See* Deposition of David Brown (GSK's Rule 30(b)(6) witness on rebate issues) dated June 3, 2009 ("Brown dep.")(Attachment B to Second Suppl. Gaier Aff.) (Ex. B hereto) at 66-70. In determining the net price to be compared with WAC here, however, even Plaintiffs' expert does not include *all* of the rebates used to calculate net revenue.. Most significantly, he leaves out all rebates paid to Medicaid, which are the most significant rebate payments that reduce GSK's net revenue. Second Suppl. Gaier Aff. (Ex. B hereto) at ¶7. Thus, even Plaintiffs' approach is not actually a true "net revenue" approach, but is an approach they concocted for this litigation.

(b) it is inconsistent with how Plaintiffs' expert has characterized and evaluated WACs before.[6] Moreover, as has previously been recognized in another Medicaid AWP case, a manufacturer's "net revenue" is an accounting concept that is so unrelated to a drug's net price to any purchaser that it is entirely irrelevant to any claim in this litigation.[7]

## II. Because Rebates to TPPs and PBMs that Reimburse on Behalf of TPPs ("Payors") Are Not Shared with Wholesalers or Providers ("Purchasers") and Have No Effect on Their Net Purchase Price, They are Simply Irrelevant Under the WAC List Price Test.

Because the WAC List Price Test was designed to compare published WACs with the net prices paid by drug purchasers, the only issue to decide here is whether the disputed manufacturer rebates to PBMs and TPPs had any effect on the net price paid by any drug purchaser.[8] As discussed below, the answer is clearly that they did not. That should end the inquiry.

The rebates at issue here are what GSK calls, in its data, "utilization rebates." These are rebates paid to TPPs and PBMs that reimburse providers, generally in

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6 In the Rule 26 Statement of Harris L. Devor filed in this case on September 30, 2008 in connection with discovery related to FUL issues (portions attached hereto as Exhibit. C), Mr. Devor did not adopt "net revenue" as his definition of WAC, but adopted a definition of WAC as "the price paid by a wholesaler (or distributor) to a manufacturer for the purchase of a particular product." He then sought to determine "corrected" WACs for the FUL drugs at issue, not by calculating the "net revenue" realized by the manufacturer for each product, but by determining the "actual, net price paid by *wholesalers and distributors* in *their* transactions with the manufacturer defendants." *Id.* at ¶¶ 16 &177. In addition, Mr. Devor previously opined in his original affidavit here that with respect to rebates to PBMs, *only* those related to their mail order pharmacy purchases (which relate to a drug purchase by an entity that buys and dispenses drugs) should be included, which GSK's expert has since done. *See* Affidavit of Harris Décor dated February 11, 2009 ("Devor's Orig. Aff.") at 10, note 2.

7 *See* Decision & Report of Discovery Master William Eich, in State of Wisconsin v. Amgen, Inc., et. al., Case No. 04 CV 1709 (May 2, 2006)(attached hereto as Exhibit D)(denying motion to compel discovery into Novartis's "net revenue" reports and calculations because they have "little, if anything, to do with the prices of Novartis's products" and because net revenue "does not correspond to any price paid by any party for Novartis drugs."); See Brown dep. (Attachment B to Second Suppl. Gaier Aff.)(Ex. B hereto) at 66-70.

8 It should be understood that all "purchased-based" rebates that GSK paid to a wholesaler, pharmacy, staff-model HMO, GPO, physician, hospital, long-term care facility, home health or surgical center or other provider have been included in *both* Plaintiffs' and GSK's WAC List Price Test analysis -- so there is no remaining dispute about those rebates. *See* Plaintiff's Supplemental Memorandum of Law In Opposition to GSK's Motion for Partial Summary Judgment ("Pl. Supp. Opp.") at 6-7. In addition, GSK has already included rebates paid due to prescriptions dispensed by PBM (and TPP)-owned mail order pharmacies which actually purchased and dispensed GSK drugs.

exchange for placement on their drug formularies and pursuant to certain targets based on the drug's "utilization" by the TPP's insured members.[9] In Plaintiff's Supplemental Opposition Brief, plaintiff seeks to create the misimpression that all GSK rebates "share all of the same characteristics."[10] In fact, there are several key characteristics that differentiate some types of rebates from others, including who gets them, whether they are later shared or passed on, and -- most importantly -- whether they affect the purchase price of a drug by any drug purchaser.

There is no dispute about how, as a general matter, the drug distribution and reimbursement system works for a brand-name drug, a system with which this Court is quite familiar.[11] Brand-name drugs are typically purchased either by wholesalers or directly by certain large providers, such as retail chain pharmacies. When wholesalers buy brand-name drugs, they resell them to "providers" such as retail pharmacies, mail order pharmacies, hospitals, physicians, nursing homes, staff model HMOs and government purchasers. A number of these provider types -- most significantly including retail pharmacies and chain pharmacies -- dispense drugs to patients after they purchase them and are subsequently "reimbursed" either directly by a TPP or by a PBM that is hired by a TPP to perform its reimbursement function. *See Id*; graphic appended as

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9 *See* Brown dep. (Attachment B to Second Suppl. Gaier Aff.) (Ex. B hereto) at 54-57; 68-74; 85-89.

10 Pl. Supp. Opp. at 7. Plaintiff also ignores the nomenclature that GSK actually uses in its data to differentiate between rebates (calling them either "purchase-based rebates" or "utilization rebates") and instead latches onto the general term "Customer rebates" that was used for accounting purposes in GSK's 20-F to describe all rebates to entities with which GSK has a business relationship. The use of the term "Customer rebates" in a Form 20-F has nothing to do with whether any particular kind of rebate should be counted for purposes of determining net purchase price under the WAC List Price Test.

11 The key aspects of the system have been described succinctly in both Professor Berndt's Affidavit and in the recent deposition of GSK's Rule 30(b)(6) witness, and are summarized in a graphic that is included as Attachment A to Dr. Eric Gaier's affidavit here. *See* Berndt Aff. (Ex. A hereto) at ¶¶ 9-16 & 28; Brown dep. at 166-82 and Exhibit 24 (attached as Attachments A and B to the Second Suppl. Gaier Aff)(Ex. B hereto).

Attachment A to the Second Supplemental Gaier Affidavit (Ex. B hereto). Wholesalers and providers that actually purchase drugs are considered to be drug "purchasers."

TPPs and PBMs that reimburse purchasers for drugs but that, themselves, do not purchase or dispense drugs are categorized as "payors." *Id.*[12] As is typical for a brand-name drug manufacturer, GSK pays rebates to PBMs and TPPs in exchange for the placement of GSK drugs on their formularies. These rebates are classic "payor" rebates, which GSK also sometimes calls "utilization" rebates. They differ in several key ways from rebates that are paid to drug purchasers. The key difference is who gets them. "Utilization rebates" are paid to payors such as PBMs or TPPs. These entities do not *purchase* the relevant GSK drug. Instead, the PBMs and TPPs typically *reimburse* a pharmacy that itself purchased and dispensed a GSK drug to a person who is covered by the relevant network. Brown dep. (Attachment B to Ex. B hereto) at 167; Berndt Aff. (Ex. A hereto) at ¶¶ 12-16.[13] The PBM or TPP is paid a "utilization rebate" based on the number of times a GSK drug is dispensed to one of their insureds by the provider that actually purchased the drug.

Significantly, these "utilization" rebates paid to PBMs and TPPs (many of which operate their own PBMs) are *not* shared in any way with any drug purchaser. Mr. Brown unequivocally so testified, Brown dep. (Attachment B to Ex. B hereto) at 175, and a widely-cited HHS study on drug pricing and reimbursement succinctly states that:

> "a negotiated rebate paid directly from the manufacturer to the PBM…does not affect the price paid by a wholesaler to a manufacturer for

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[12] Note that, at least for purposes of this Motion, both GSK and the Plaintiff characterize mail order pharmacies owned by PBMs as "purchasers," not payors, and both sides "count" (for purposes of the WAC List Price Test) rebates paid to them that are attributable to drug purchases by them.

[13] If a PBM is reimbursing a pharmacy on behalf of a TPP, it typically gets paid a negotiated amount by the TPP to cover the reimbursement costs (sometimes more) and typically passes on to its TPP clients all or part of the "utilization rebate" it receives from GSK. *See* Berndt Aff. (Ex. A hereto) at ¶ 14; Second Suppl. Gaier Aff. (Ex. B hereto) Attachment A and ¶¶ 8, 10 (with additional citations).

> the drug, the price paid by a retail pharmacy to the wholesaler, or the price paid by the PBM to the pharmacy."[14]

Thus, because there is no dispute that a manufacturer rebate paid to a reimbursing payor such as a PBM or TPP has no impact on the price paid by the actual purchaser of GSK's drugs, such rebates are completely irrelevant to the computation of any purchaser's net price under the WAC List Price Test. To conclude otherwise would be to indulge the complete fiction now being advocated by Plaintiffs: that payor rebates reduce purchaser prices, as opposed to the net cost of payor reimbursements.[15]

## III. Manufacturer Rebates to "Payors" Actually *Reduce* the Payors' Net Cost of Reimbursement.

It makes no sense to include rebates paid to payors in the WAC List Price Test because those rebates actually benefit the very type of entities that have been plaintiffs throughout the AWP litigation -- the third-party payors. As Professor Berndt has explained, rebates to payors such as PBMs and TPPs actually "reduce the payors' cost of reimbursing for drugs, and, ultimately, the health care premiums paid by consumers," Berndt Aff. (Ex. A hereto) at ¶ 24, and such rebates should be encouraged, not used as the basis for additional liability and damages. *Id.*; *see* Berndt Aff. (Ex. A hereto) at ¶¶ 20-30.

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[14] HHS report to the President, "Prescription Drug Coverage, Spending, Utilization, and Prices," April 2000, Chapter 3, p. 7. This Report is available on the Internet at http://aspe.hhs.gov/health/reports/drugstudy/chap03.htm. Professor Berndt also states that rebates to PBMs and other payors (other than for certain mail order sales which GSK has included here) "have no impact on the net price paid by the wholesaler or provider." *See* Berndt Aff. (Ex. A hereto) at ¶ 28.

[15] GSK's position that utilization rebates to PBMs should *not* be included in assessing drug purchaser prices is not a new, litigation-driven position. In fact, during the entire 1997-2005 period, GSK *did not include* in its calculation of "Average Manufacturer's Price" ("AMP") under Medicaid *any* "utilization rebates" paid to PBMs or TPPs, even those attributable to prescriptions dispensed by PBM-owned mail order pharmacies. Brown dep. (Attachment B to Ex. B hereto) at 176-178. Had GSK *included* any of these rebates in its AMP calculations, its reported AMPs would have been lower, and the Medicaid rebates to New York and the other states would have gone down. In other words, GSK's position on this issue -- well before this litigation began -- was taken despite the fact that it was more costly to GSK than the opposite position would have been. *Id.* at 180-81.

The following simple hypotheticals show the difference between rebates paid to purchasers and rebates paid to payors, to illustrate this point.

**Hypothetical # 1: Rebate Paid to Purchaser**

Assume:

- WAC = $100
- AWP = $125 (reflecting a standard 25% mark-up)
- Reimbursement = $110 (AWP-12%)
- Provider purchase price = $100 (WAC)
- Manufacturer Rebate paid to the **provider/purchaser** = $10, which causes
- Net provider purchase price = $90
- Net Payor Reimbursement Cost = $110

Both GSK and Plaintiffs *agree* that this particular sale would *flunk* the WAC List Price Test, since the provider/purchaser got a rebate that caused it to pay, on a net basis, $90, which is 10% less than the WAC of $100.

**Hypothetical # 2: Rebate Paid to Payor**

Assume:

- WAC = $100
- AWP = $125 (reflecting a standard 25% mark-up)
- Reimbursement = $110 (AWP-12%)
- Provider purchase price = $100 (WAC)
- Manufacturer rebate paid to **payor** = $10, which causes
- Net provider purchase price = $100
- Net Payor Reimbursement Cost = $100

Note in this second scenario that the provider's net purchase price remains $100 because the rebate went to the payor instead of the provider/purchaser. This sale should *pass* the WAC List Price test because the rebate had no impact whatsoever on the provider/purchaser's original net price of WAC, which is all that matters. In fact, the rebate had the added benefit of reducing the payors' cost by $10.

But under Plaintiffs' latest interpretation of the WAC List Price Test, this transaction would *fail* the test even though (a) the provider/purchaser paid the same amount ($100, i.e. WAC) for the drug despite the rebate, (b) the payor's net cost of reimbursement was reduced by $10 due to the rebate, and (c) the $10 rebate to the payor actually narrowed -- indeed eliminated -- the difference between what the provider paid to buy the drug and what it cost the payor to reimburse for the drug. This absurd outcome is exactly what would result if the Court adopts the New York Counties' latest interpretation of the WAC List Price Test, an outcome that Professor Berndt has said would "defeat the purpose of the WAC List Price Test" and penalize GSK for paying rebates that effectively reduce health care costs. Berndt Aff. (Ex. A hereto) at ¶¶ 29-30.

## IV. In Addition to Inappropriately Including PBM and TPP Utilization Rebates In His WAC List Price Test Analysis, Plaintiff's Expert Also "Misallocates" Those Rebates In a Way that Causes Drugs Purchased By Retail Pharmacies that Did *Not* Get The Rebates To "Flunk."

In addition to inappropriately including utilization rebates that have no effect on the net price paid by any drug purchaser in his WAC List Price Test "net price" calculations, Plaintiffs' expert compounds his error by "misallocating" the disputed rebates in a way that suffers from flaws that are similar to those that infected his originally recommended allocation of chargebacks to all wholesaler sales. As the Court may recall from the extensive discussion at the April 16, 2009 oral argument on GSK's motion, Mr. Devor previously allocated all chargebacks as if they were discounts to

wholesalers and then claimed that the chargebacks caused many sales that did not involve chargebacks at all to flunk the WAC list price test. Mr. Devor's latest affidavit (and accompanying computer programs) reveals that he has abandoned this inappropriate way of handling *wholesaler chargebacks,* and has now adopted an approach to *them* that is quite similar to the approach used by GSK's expert, Dr. Gaier. Second Suppl. Gaier Aff. (Ex. B hereto) at ¶ 2 note 3 and ¶ 4.

However, Mr. Devor now treats the disputed *PBM and TPP rebates* in a similarly flawed way. That is, Mr. Devor now effectively "allocates" the disputed payor rebates to purchasing entities that never received them. In other words, Mr. Devor attributes to retail pharmacy purchasers the vast majority of the utilization-based rebates that GSK actually paid to PBMs and TPPs. The result is that a large number of sales to retail pharmacy purchasers are "failed" in the WAC test because of the utilization-based rebates that GSK paid to the payors -- rebates that the retail pharmacy purchasers did not receive. Second Suppl. Gaier Aff. (Ex. B hereto) at ¶ 12. This sleight of hand inappropriately causes a significant number of sales to retail pharmacies -- sales which were actually made through wholesalers at prices near WAC -- to "flunk" the test. Once again, Plaintiffs strain mightily to find a way to "flunk" GSK brand-name drugs, but once again they cannot overcome the fact that over 75% of the time these drugs were sold into the retail pharmacy or chain pharmacy channels within 5% of WAC.[16]

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[16] As Dr. Gaier states in his Second Supplemental Affidavit (Ex. B hereto) at ¶ 18:

> The fundamental reason that the GSK drugs at issue pass the WAC test is that, regardless of Mr. Devor's flawed attempts to "fail" GSK NDCs at issue, the fundamental facts are that (1) 62.6% of the GSK drugs at issue in the motion are sold through wholesalers to retail pharmacies with no GSK contract, and virtually all of these sales were made within 5% of WAC, and (2) most of GSK's direct sales (e.g., its sales to chain pharmacies), which account for another 17.3% of GSK's sales, were also made within 5% of WAC. That is, in the aggregate more than 75% of GSK's sales of the NDCs at issue were made through the two sales channels where there is very little discounting for brand-name drugs. No matter what discounts or rebates were provided by GSK when drugs were sold through *other* sales channels (such as sales to hospitals and entities like the V.A.), the majority of which are *not* reimbursed by Medicaid, the WAC test is easily passed

## V. Plaintiffs Raise a Number of "Red Herring" Arguments That Should Be Rejected.

As discussed in the Introductory section above, Plaintiffs seek to defeat GSK's motion by raising three "red herring" arguments, each of which should be rejected.

First, Plaintiffs argue in their latest brief that GSK's payment of rebates to TPPs and PBMs in exchange for placement of GSK drugs on formularies (and utilization of those drugs by the TPP's insureds) is like giving discounts to physicians for physician-administered drugs and then improperly marketing the "spread" between their acquisition cost and the published AWP. This is pure sophistry. Professor Berndt -- who has previously expressed concerns with "spreads" created by discounting to physicians and then marketing the difference between physician acquisition cost and AWP-based reimbursements -- considers marketing through the payment of manufacturer rebates to PBMs and other payors to be quite a different thing. He states "I take it as a given that GSK is motivated to offer rebates to PBMs and other payors because it expects that these rebates will result in formulary placement and increased utilization for its drugs. Economists generally regard this sort of competition which reduces the payors' cost of reimbursing for drugs as being beneficial. ... All else being equal, such rebates reduce the cost of health care, and should be encouraged." Berndt Aff. (Ex. A hereto) at ¶ 25; see generally ¶¶ 23-30. Plaintiffs' attempt to compare the payment of rebates to payors to marketing the spread to doctors has no merit whatsoever..[17]

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because well over 50% of the sales of brand-name drugs are made with little discounting to the retail and chain pharmacy channels. That is a fundamental fact of the economics of the brand-name business model. *See also* Second Suppl. Gaier Aff. (Ex. B hereto) Attachment G (graphic which shows percentages of GSK drugs distributed to various provider types).

[17] Interestingly, Plaintiffs do not contend that either the basic Medicaid rebate or any negotiated supplemental Medicaid rebate -- which clearly benefit the Medicaid program and together are by far the largest utilization-based rebates paid by GSK -- should be included in the WAC List Price Test. Yet they seek to create the misimpression that there is something different and nefarious about other

Second, Plaintiffs try to hide behind the complexity of the facts, implying that there are still technical or other disputes that preclude summary judgment. This is simply incorrect. In fact, during the course of the extensive briefing process concerning this Motion, the fundamental analysis of each side's expert has converged to the point where the only remaining issue that matters to the outcome is whether and how to include non-mail order rebates to PBMs and TPPs in the calculation of the relevant net prices. Virtually all of the 208 GSK NDCs originally placed at issue in GSK's motion still pass the WAC List Price Test even if Dr. Gaier's very conservative "alternative calculations" (which take into account Plaintiffs' prior criticisms of his original analysis) form the basis for the results. Under that analysis, 206 of the original 208 NDCs still pass. Second Suppl. Gaier Aff. (Ex. B hereto) at ¶ 14 and Attachments C and D. Alternatively, once the payor rebates described herein are properly excluded (and the remaining rebates are properly allocated to the purchasers who got them), 205 of the original 208 NDCs pass the test even when *Mr. Devor's* programming and methodology for performing the WAC List Price Test is used. *Id.* at ¶ 15 and Attachments E and F.

Finally, Plaintiffs' expert seeks to create the misimpression that many of the GSK drugs at issue "flunk" the "AWP Spread Test," even though GSK has not moved on the basis of that test and need not satisfy it in order to prevail here. As Dr. Gaier's Second Supplemental Affidavit demonstrates, however, the only issue that now separates Mr. Devor's AWP Spread Test results from Dr. Gaier's is the treatment of rebates to PBMs and TPPs. Mr. Devor, who previously (and correctly) did not count these payor rebates *at all* in his original AWP Spread Test calculations (though he made other errors), has now reversed his position and includes them. As demonstrated above, these rebates have

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utilization rebates paid to other payors, which similarly benefit those other payors and similarly reduce the overall costs of health care.

absolutely no effect on the average net price paid by providers reimbursed by the New York Medicaid program, and they should be excluded for all of the reasons set forth in our discussion of the WAC List Price Test above. Once those rebates are properly excluded from the analysis of the relevant providers' net purchase price (as Mr. Devor originally did and as Dr. Gaier has done all along), the result is that all but a handful of the GSK NDCs at issue pass the AWP Spread Test as well. Second Suppl. Gaier Aff. (Ex. B hereto) at ¶¶ 19-22.

**Conclusion**

For all of the reasons set forth in GSK's Opening Brief, in its Reply Brief, and in this Supplemental Brief, this Court should grant GSK's motion for partial summary judgment and enter an Order that grants judgment in GSK's favor on all of the New York Counties' WAC/AWP claims with respect to all of the NDCs that pass the WAC List Price test.

Dated: July 2, 2009

Respectfully submitted,

Defendant SmithKline Beecham Corporation, d/b/a GlaxoSmithKline ("GSK")

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**CERTIFICATE OF SERVICE**

I hereby certify that today I have caused an electronic copy of the foregoing Defendant SmithKline Beecham Corporation, d/b/a GlaxoSmithKline's ("GSK's") Supplemental Brief, Concerning Rebate Issue, in Support of Its Motion for Partial Summary Judgment in the New York County Cases (together with all accompanying affidavits and exhibits) to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL No. 1456 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: July 2, 2009

/s/ Frederick G. Herold
Frederick G. Herold